

**REMARKS**

Claims 1-32 are pending in the application. Claims 1-9, 12-26 and 29-32 are rejected. Claims 10, 11, 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

Reconsideration of the claim rejections and allowance of all the pending claims in view of the following remarks are respectfully requested.

**Claim Rejections – 35 U.S.C. § 102**

Claims 1-4, 16, 17, and 23-25 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Pagay et al., US 5,411,488 ("Pagay"). Independent claim 1 is directed to a flush syringe assembly comprising, *inter alia*, means for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped. Independent claim 23 is directed to an I.V. flush syringe assembly comprising, *inter alia*, structure for moving additional flush solution distally in the passageway of the barrel after flush solution has been delivered from the chamber and distal motion of the plunger with respect to the barrel has stopped, the structure including the stopper having a distal end including a distal wall and a cavity therein defining an inside surface and a proximal end, the distal wall being flexible enough to collapse at least partially into the cavity under the liquid pressure and to move back toward its original shape at the completion of the flush procedure to force additional flush solution of at least 0.001 ml into the passageway when the syringe is connected to a peripheral catheter.

According to the Examiner, Pagay discloses:

a barrel (20, the barrel) including a cylindrical side wall  
(21) having an inside surface defining a chamber for

retaining fluid, an open proximal end (24, the open end located near the finger grips) and a distal end (22, tapered tip) including a distal wall with a tip extending distally therefrom having a passageway (Fig. 2, the barrel) therethrough in fluid communication with said chamber; a plunger (50, plunger) including an elongate body portion having a proximal end and a distal end, a stopper (30) slidably positioned in fluid-tight engagement with said inside surface of said barrel for driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; and means for moving (64, plunger rod tip) additional fluid distally in said passageway at the completion of the flush procedure after distal motion of said plunger with respect to said barrel has stopped.

Applicants respectfully traverse this basis for rejection.

It has long been the law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631, 638 (Fed. Cir. 1987). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But disclosure of each element is not quite enough – this court has long held that

'[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.*'") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original)).

Claim 1 is written in means-plus-language and is directed to a flush syringe assembly comprising, *inter alia*, means for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped. To anticipate a claim reciting a means-plus-function limitation, the reference must disclose the recited function identically. See *Transclean Corp. v. Bridgewood Servs.*, 290 F.3d 1364, 1372 (Fed. Cir. 2002). However, as noted in the MPEP, identity of function is not the only requirement to anticipate or render obvious a means-plus-function claim limitation: one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure. See *In re Donaldson*, 16 F.3d 1189, 1193 (Fed. Cir. 1994). Thus, to determine whether a claim limitation is met, where expressed as a means for performing a stated function, the fact finder must compare the accused structure with the disclosed structure, and must find identical or equivalent structure as well as identity of claimed function for that structure. See *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987). "[A]bsent structure [in a prior art reference] which is capable of performing the functional limitation of the 'means,' [the prior art reference] does not meet the claim." *In re Mott*, 557 F.2d 266, 269 (CCPA 1977).

Structure provided in the instant specification for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped includes a stopper including a distal end having a distal wall and a cavity therein defining an inside surface and a proximal end, the distal wall being flexible enough to collapse at least partially into the cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into the passageway of the barrel. This structure, which is diagrammatically shown in Figures 3-5 (stopper 41, distal wall 62, cavity 59), is the means recited in claim 2 and the structure recited in claim 23. Additional structure which may be provided in addition to the flexible plunger wall to aid in the recited function includes a spring (element 382 in Figure 12), a projection (element 482 in Figure 15) and a raised rib (element 281 in Figure 11).

According to the Examiner, the plunger rod tip 64 in Pagay is the structure capable of forcing additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. However, the recited function requires that the distal motion of the plunger has stopped. Clearly, the only way that plunger rod tip 64 could force additional fluid out of the barrel is if the plunger continues to move distally. Thus, plunger rod tip 64 is not identical or equivalent structure capable of performing the identical recited function.

Regarding claims 2 and 23, which recite specific structure for performing the recited function, the Examiner states that Pagay discloses said stopper including a distal end having a distal wall (32, convex side) and a cavity (34, interior) therein defining an

inside surface and a proximal end, said distal wall being flexible enough to collapse at least partially into said cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into said passageway. However, the Examiner has provided no evidence that distal wall 32 is flexible enough to at least partially collapse into cavity 34 under liquid pressure. Indeed, a review of Pagay indicates that that this is not the case at all.

As shown in Figure 5 of Pagay, plunger tip 64 contacts the inside face 34 of stopper during use. As a result, there is no cavity into which the stopper could partially collapse. Indeed, Figure 5 shows elongation of the distal face 32 of the stopper in the distal direction, which aids in movement of the barrel in the distal direction. *See* col. 6, line 60 to col. 7, line 2. Furthermore, Pagay teaches that upon stoppage of distal motion of the plunger, a vacuum is created in the barrel, which draws fluid into the passageway (see col. 6, lines 56-60), which is the complete opposite of the function recited in claims 1 and 23, namely forcing additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. As such, Pagay fails to disclose identical or equivalent structure capable of performing the identical recited function.

Accordingly, Applicants submit the claims 1-4, 16, 17, and 23-25 are not anticipated by Pagay, and reconsideration of this basis for rejection is respectfully requested.

#### **Claim Rejections – 35 U.S.C. § 103**

a. Claims 5-8, 18-21 and 26 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pagay. The Examiner acknowledges that Pagay does not explicitly

disclose the additional limitations recited in the claims, but states that such limitations are the result of routine experimentation and design choice.

Applicants respectfully traverse this basis for rejection.

Claims 5-8 and 18-21 each depends from independent claim 1, and claim 26 depends from independent claim 23. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). As discussed above with respect to the rejections of claims 1 and 23, Pagay does not disclose any structure capable of moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped.

Accordingly, Applicants submit the claims 5-8, 18-21 and 26 are not unpatentable over Pagay, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pagay in view of Grimard, US 5,795,337 ("Grimard"). The Examiner acknowledges that Pagay does not explicitly disclose the additional limitations recited in the claims, but states that such limitations are found in Grimard.

Applicants respectfully traverse this basis for rejection.

Claims 9 and 22 each depends from independent claim 1. As discussed above with respect to the rejection of claim 1, Pagay does not disclose any structure capable of moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. Furthermore, the Examiner has pointed to nothing in Grimard that remedies the deficiency of Pagay in this respect. As such, the combination of Grimard with Pagay

cannot render the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, Applicants submit the claims 9 and 22 are not unpatentable over Pagay in view of Grimard, and reconsideration of this basis for rejection is respectfully requested.

c. Claims 12-15 and 29-32 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pagay in view of Eykmann et al, US 5,620,423 ("Eykmann"). The Examiner acknowledges that Pagay does not explicitly disclose the additional limitations recited in the claims, but states that such limitations are found in Eykmann.

Applicants respectfully traverse this basis for rejection.

Claims 12-15 each depends from independent claim 1, and claims 29-32 each depends from independent claim 23. As discussed above with respect to the rejections of claims 1 and 23, Pagay does not disclose any structure capable of moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. Contrary to the Examiner's assertion, nothing in Eykmann remedies the deficiency of Pagay in this respect.

Each of claims 12-15 and 29-32 requires a stopper including a distal end having a distal wall and a cavity therein defining an inside surface and a proximal end, the distal wall being flexible enough to collapse at least partially into the cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into the passageway of the barrel. In contrast, stopper 6 shown in Figure 2 of Eykmann is prestressed in the proximal direction, which is its initial shape after it has been displaced after cartridge 2

has been filled with a viscous material, as shown in the right side of Figure 3. *See* col. 5, lines 36-39. After engagement by rotary piston 4, stopper 6 curves in the opposite direction, i.e., in the distal direction, as shown in the left side of Figure 3. *See* col. 5, lines 45-48. After delivery of the desired quantity of material, rotary piston 4 is turned in the opposite direction, thereby removing pressure from stopper 6, allowing it to return to its original shape. *See* col. 5, lines 56-62. As Eykmann teaches, this generates an underpressure, which pulls the material which is still in the discharge opening 23 of the discharge nozzle 9 back into cartridge 2, thereby preventing running or dripping of material. *See* col. 5, lines 62-67.

Thus, the original shapes of the stoppers in the instant claims (extended distally) vs. Eykmann (collapsed proximally) result in different functions. That is, rather than *forcing* additional fluid into the passageway of the barrel after distal motion of the plunger has stopped, as recited in the instant claims, the stopper in Eykmann does the complete opposite, namely *drawing* material into the barrel after distal motion of the plunger has stopped. As such, the combination of Eykmann with Pagay cannot render the claimed invention obvious. *See Rijckaert*, 9 F.3d at 1533.

In addition, contrary to the Examiner's assertion, the missing limitations of claims 12-15 and 29-32 are not found in Eykmann. Claims 12 and 29 each requires the inside surface of the stopper include a proximally directed projection configured to compress when the stopper is in a collapsed position and to urge the distal wall from the collapsed position toward its original shape. This is diagrammatically shown in Figure 15 (element 482) of the instant application. The Examiner states that Figure 2 of Eykmann shows a proximally directed projection, but Figure 2 merely shows stopper 6, with no indication of a proximally directed projection attached thereto.



Claims 13 and 30 each requires at least one rib on said inside surface of the stopper at the distal wall configured to deflect when the stopper is in a collapsed position and urge the distal wall from the collapsed position toward its original shape. This is diagrammatically shown in Figures 10 and 11 (element 281) of the instant application. The Examiner states that element 15 in Figure 2 is the claimed rib, but element 15 is not on the inside surface of the stopper, as required by the claims, but rather on the outside surface.

Claims 14, 15, 31 and 32 each requires the distal wall have an area of reduced thickness to lower the pressure required for the distal wall to collapse. This is diagrammatically shown in Figures 8 and 9 (elements 168 and 169) of the instant application. The Examiner states that element 13 in Figure 2 is the area of reduced thickness, but Eykmann teaches that stopper 6's original position is collapsed (*see* col. 4, line 67 to col. 5, line 2), meaning element 13 does not function to lower the pressure required for the distal wall to collapse during distal movement of the plunger.

Accordingly, Applicants submit the claims 12-15 and 29-32 are not unpatentable over Pagay in view of Eykmann, and reconsideration of this basis for rejection is respectfully requested.

**CONCLUSION**

It is believed that claims 1-32 are now in condition for allowance, early notice of which would be appreciated. The Examiner is authorized to charge any additional fees or credit any overcharges to Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

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Respectfully submitted,

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